IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
GRAND RAPIDS DIVISION

CLAUDE HOWARD, an individual	§	
Plaintiff,	§	
vs.	§	**CASE NO. _____**
COOK INCORPORATED; COOK MEDICAL INCORPORATED; COOK GROUP INCORPORATED; COOK MEDICAL, LLC; WILLIAM COOK EUROPE APS,	§	**JURY TRIAL DEMANDED**
Defendants.	§	

COMPLAINT

Plaintiff Claude Howard, by and through his undersigned attorneys, hereby sues Defendants Cook Incorporated, Cook Medical Incorporated, Cook Group Incorporated, Cook Medical, LLC, and William Cook Europe APS and alleges as follows:

PARTIES

1. Plaintiff Claude Howard ("Plaintiff") is an individual who, at all times relevant to allegations herein, resided in, continues to reside in, and is a citizen of the State of Michigan.

2. Defendant Cook Incorporated, is incorporated under the laws of the State of Indiana with its principle place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Cook Incorporated was and is a foreign corporation doing business in the State of Michigan, including Kent County. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the inferior vena cava filter ("IVC Filter") known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At

all times relevant hereto, Defendant Cook Incorporated was engaged in business, has conducted substantial business activities, and derived substantial revenue from within Michigan. Defendant has also carried on solicitations or service activities in Michigan. The registered agent for Cook Incorporated is Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, IN 46204. Cook Incorporated may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent. However, a request to waive service will be delivered in accordance with Fed. R. Civ. P. 4(d).

3. Defendant Cook Incorporated is the parent company of Defendant Cook Medical Incorporated. Defendant Cook Medical Incorporated was incorporated under the laws of the State of Indiana with its principle place of business located at 111 Monument Circle, Suite 4000, Indianapolis, Indiana 46204. On or about Janaury 1, 2014 Cook Medical Incorporated converted into an Indiana limited liability corporation named Cook Medical, LLC. At all times relevant to this cause of action Cook Medical Incorporated was a foreign corporation doing business in the State of Michigan, including Kent County. At all times relevant to this action, Cook Medical Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the IVC filter known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Defendant Cook Medical Incorporated was engaged in business in Michigan has conducted substantial business activities and derived substantial revenue from within Michigan. This Defendant has also carried on solicitations or service activities in Michigan. The registered agent for Cook Medical Incorporated is Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, IN 46204. Cook Medical Incorporated may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to

its registered agent. However, a request to waive service will be delivered in accordance with Fed. R. Civ. P. 4(d).

4. Defendant Cook Group Incorporated, is incorporated under the laws of the State of Indiana with its principle place of business located at 750 N. Daniels Way, Bloomington, IN 47404. Cook Group Incorporated is a foreign corporation doing business in the State of Michigan, including Kent County. At all times relevant to this action, Cook Group Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and sold the IVC filter known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Defendant Cook Group Incorporated was engaged in business, has conducted substantial business activities, and derived substantial revenue from within Michigan. Defendant has also carried on solicitations or service activities in Michigan. The registered agent for Cook Group Incorporated is Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, IN 46204. Cook Group Incorporated may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent. However, a request to waive service will be delivered in accordance with Fed. R. Civ. P. 4(d).

5. Defendant Cook Incorporated is the parent company, sole shareholder, and only member of Defendant Cook Medical, LLC. Cook Incorporated is an Indiana Corporation with its principle place of business in Indiana. Cook Medical, LLC is a limited liability company incorporated under the laws of the State of Indiana with its principle place of business at 1025 West Acuff Road, Bloomington, IN 47404. Cook Medical, LLC is a foreign limited liability corporation which at all time relevant to this cause of action was doing business in the State of Michigan, including Kent County. At all times relevant to this action, Cook Medical, LLC

designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the IVC filter known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Cook Medical, LLC was registered to do business with Michigan. At all times relevant hereto, Defendant Cook Medical LLC was engaged in business in Michigan, has conducted substantial business activities and derived substantial revenue from within Michigan. Defendant has also carried on solicitations or service activities in Michigan. The registered agent for Cook Medical, LLC is Corporation Service Company, 251 East Ohio Street, Suite 500, Indianapolis, IN 46204. Cook Medical, LLC may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent. However, a request to waive service will be delivered in accordance with Fed. R. Civ. P. 4(d).

6. Defendant William Cook Europe APS ("Defendant Cook Europe") is organized under the laws of Denmark and its business form most closely resembles that of an American corporation. It is a foreign corporation that regularly conducts business in the State of Michigan. Defendant William Cook Europe's headquarters is based at Sandet 6 Bjaeverskov 4632, Denmark. A request to waive service will be delivered in accordance with Fed. R. Civ. P. 4(d).

7. Defendants Cook Incorporated, Cook Incorporated a/k/a Cook Medical Incorporated, Cook Group Incorporated, Cook Medical, LLC, and William Cook Europe APS shall be referred to herein individually by name or collectively as the "Cook Defendants."

8. At all times alleged herein, Cook Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

9. At all times herein mentioned, each of the Cook Defendants were the agents, servants, partners, predecessors in interest, and joint venturers of each other, and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

JURISDICTION AND VENUE

10. Personal jurisdiction is proper pursuant to O.C.G.A § 9-10-91 and 28 U.S.C. § 1332. The Cook Defendants have conducted and continue to conduct substantial and systematic business activities related to their IVC filters, including the Gunther Tulip™ Vena Cava Filter (hereinafter "Cook Tulip filter") at issue in this case, in this jurisdiction. Such activities include, but are not limited to: (a) sales of IVC filters, including the Cook Tulip filter at issue in this case, in this jurisdiction; (b) hiring, training, and deploying employees, including managers and sales representatives, in this jurisdiction; (c) advertising and marketing of their IVC filters, including the Cook Tulip filter at issue in this case, in this jurisdiction; (d) maintenance of company files and equipment relating to the Cook Tulip filter in this case, in this jurisdiction; (e) payment of employee salaries in this jurisdiction; and (f) maintenance of a website directed to all states, including Michigan. Defendant Cook Medical LLC is registered to do business in State of Michigan. The Cook Defendants also committed tortious acts within Michigan and caused injury to persons or property within Michigan arising out of acts or omissions by the Cook Defendant outside this state at or about the time of the Plaintiff's injury, while the Cook Defendants were engaged in solicitation or service activities within Michigan, and/or while products, materials, or things processed, serviced, or manufactured by the Cook Defendants were used or consumed within Michigan in the ordinary course of commerce, trade, or use.

11. There is complete diversity between the parties and the amount in controversy exceeds $75,000, exclusive of interest and costs. *See* 28 U.S.C. § 1332.

12. Venue is properly laid pursuant to 28 U.S.C. § 1391(b)(2) and (d), as the Cook Defendants' Tulip filter failed in Kent County, Michigan, and the Defendants are corporations subject to personal jurisdiction in the district.

13. Plaintiff's claims in this action are brought solely under state law. Plaintiff does not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. § 1331.

ALTERNATIVE ALLEGATIONS

14. To the extent any allegation herein is inconsistent with any other allegation, such inconsistent allegations are pleaded in the alternative pursuant to Fed. R. Civ. P. 8(d)(3).

GENERAL FACTUAL ALLEGATIONS

15. Plaintiff brings this case for serious, life-threatening injuries he suffered, and will continue to suffer, as a result of the Cook Defendants' surgically implanted medical device, the Cook Gunther Tulip filter, that was implanted at Spectrum Health Hospital in Grand Rapids, Michigan on November 30, 2005.

16. Cook Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell products such as IVC filters that are sold to and marketed as both permanent and retrievable devices to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such product is the Cook Tulip filter.

17. Cook Defendants sought Food and Drug Administration ("FDA") clearance to market the Cook Tulip filter and/or its components under Section 510(k) of the Medical Device Amendment.

18. On or about October of 2000, the Cook Defendants obtained FDA clearance to market the Cook Tulip filter under Section 510(k) of the Medical Device Amendment as a permanent IVC filter.

19. On or about October 31, 2003, the Cook Defendants obtained FDA clearance to market the Cook Tulip under Section 510(k) of the Medical Device Amendment as a retrievable IVC filter.

20. Section 510(k) allows marketing of medical devices if the manufacturer claims the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device. The device is then cleared by the FDA under Section 510(k). The Cook Defendants claimed that the Cook Tulip filter was substantially equivalent to the Greenfield and LGM Vena Tech IVC filters.

21. An IVC filter like the Cook Tulip filter is a device ostensibly designed to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs. IVC filters are marketed as being safely implanted, either temporarily or permanently, within the vena cava.

22. The inferior vena cava ("IVC") is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. These thrombi can develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. If the thrombi reach the lungs, they are considered "pulmonary emboli" or PE.

23. An IVC filter, like the Cook Tulip filter, is ostensibly designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

24. The Cook Tulip filter has four (4) anchoring struts for fixation with webbed wires (like tulip petals) between each of the anchoring structs.

25. On or about November 30, 2005, Plaintiff was implanted with a Cook Tulip IVC filter at Spectrum Health Hospital in Grand Rapids, Michigan to avoid the risk of pulmonary embolism. The Cook Tulip filter appropriately placed infrarenally in Plaintiff was stated to be appropriate for use as a permanent filter or a retrievable filter.

26. On or about July 31, 2018, Plaintiff underwent a computerized tomography scan ("CT scan") of his abdomen at Blodgett Hospital in Grand Rapids, Michigan.

27. On or about June 15, 2020, Plaintiff was informed that the CT scan revealed that the struts of the Cook Tulip filter had perforated outside of the wall of the IVC.

28. Plaintiff's injury was inherently undiscoverable or objectively verifiable such that, despite Plaintiff's reasonable diligence, he was unable to discover his injury until on or about June 15, 2020.

29. Plaintiff faces numerous health risks, including the risks of death. Plaintiff will require ongoing medical care and monitoring for the rest of his life.

30. At all times relevant hereto, the Cook Tulip filter was widely advertised and promoted by the Cook Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

31. At all times relevant hereto, the Cook Defendants knew their retrievable IVC filters were defective and knew that the defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

32. The Cook Defendants failed to disclose to physicians and patients, including Plaintiff and his healthcare providers, that their retrievable IVC filters, including the Cook Tulip filter, were subject to breakage, collapse, causing thrombus, and/or risk of damage to the vena cava wall.

33. At all times relevant hereto, the Cook Defendants continued to promote their retrievable IVC filters, including the Cook Tulip filter, as safe and effective, even though the clinical trials that had been performed were not adequate to support long- or short-term efficacy.

34. The Cook Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its IVC filters, including the Cook Tulip filter, as aforesaid.

35. At all times relevant hereto, the Cook Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Tulip filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

36. The Cook Tulip filter was designed, manufactured, distributed, sold, and/or supplied by the Cook Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of the Cook Defendants' knowledge of the product's failure and serious adverse events.

37. At all times relevant hereto, the officers and/or directors of the Cook Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

STATUTE OF LIMITATIONS TOLLING

38. Plaintiff incorporates by reference the factual portion of this petition as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows.

39. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

40. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Cook Tulip filter and the Cook Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

41. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by the Cook Defendants when they had a duty to disclose those facts. The Cook Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of his claims, without any fault

or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on his causes of action. The Cook Defendants' fraudulent concealment did result in such delay.

42. The Cook Defendants are estopped from relying on the statute of limitations defense because the Cook Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Gunther Tulip Filter.

43. The Cook Defendants were and remains under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. The Cook Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which it must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

44. At all times herein mentioned, the Cook Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

45. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Cook Defendants such that any individuality and separateness between them have ceased and these Cook Defendants are alter egos. Adherence to the fiction of the separate existence of these Cook Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

46. At all times herein mentioned, the Cook Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

47. At all times herein mentioned, the officers and/or directors of the Cook Defendants participated in, authorized and/or directed the production, marketing, promotion, and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I
NEGLIGENCE

48. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

49. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Cook Tulip filter.

50. The Cook Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed, and sold the Cook Tulip filter that was implanted into Plaintiff.

51. The Cook Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Cook Tulip filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

52. The Cook Defendants knew or should have known that the Cook Tulip filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

53. At the time of manufacture and sale of the Cook Tulip filter (2000 until Present), the Cook Defendants knew or should have known that:

a. The Cook Tulip filter was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. The Cook Tulip filter was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. The Cook Tulip filter was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall;

d. The Cook Tulip filter was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

e. There were no clinical trials which adequately established the efficacy of filter in preventing pulmonary embolisms.

54. At the time of manufacture and sale of the Cook Tulip filter (2000 until Present), the Cook Defendants knew or should have known that using the Cook Tulip filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; thrombus, cardiac arrhythmia, and other symptoms similar to myocardial infraction; perforations of tissue, vessels, and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional

medical and surgical procedures including general anesthesia, with the attendant risk of life threatening complications.

55. The Cook Defendants knew or should have known that consumers of the Cook Tulip filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

56. The Cook Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Cook Tulip filter in, among others, the following ways:

a. Designing and distributing a product which the Cook Defendants knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiff, Plaintiff's physicians, Plaintiff's agents, or the general health care community about the Cook Tulip filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of the Cook Tulip filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Cook Tulip filter;

g. Advertising, marketing and recommending the use of the Cook Tulip filter, while concealing and failing to disclose or warn of the dangers known by Cook Defendants to be connected with and inherent in the use of the Cook Tulip filter;

h. Representing that the Cook Tulip filter was safe for its intended use when in fact, the Cook Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing to manufacture and sell the Cook Tulip filter with the knowledge that the product was dangerous and not reasonably safe;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Gunter Tulip filter so as to avoid the risk of serious harm associated with the use of the Cook Tulip filter;

k. Advertising, marketing, promoting and selling the Cook Tulip filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Cook Tulip filter; and,

m. Failing to establish and maintain an adequate post-market surveillance program.

57. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

58. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

59. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

60. The Cook Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Cook Tulip filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

61. At the time the Cook Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of

commerce, the Cook Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

62. Specifically, the Cook Defendants knew or should have known at the time they manufactured, labeled, distributed, and sold the Cook Tulip filter that was implanted into Plaintiff that it posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting in serious injuries.

63. Consequently, the Cook Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

64. The Cook Defendants further had a duty to warn of dangers and proper safety instructions that they became aware of even after the device was distributed and implanted into Plaintiff.

65. Despite their duties, the Cook Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Gunter Tulip filter, and further failed to adequately provide instructions on the safe and proper use of the device. These failures rendered the Cook Tulip filter unreasonably dangerous to Plaintiff.

66. No health care provider or patient, including Plaintiff and his healthcare providers, would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

67. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

68. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

69. Therefore, the Cook Tulip filter implanted into Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling, and/or instructions accompanying the product.

70. The Cook Tulip filter implanted into Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by the Cook Defendants.

71. As a direct and proximate result of the Cook Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT III
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

72. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

73. At all times relevant to this action, the Cook Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, and sold into the stream of commerce the Cook Tulip filter, including the one implanted in Plaintiff.

74. The Cook Tulip filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left the Cook Defendants possession. In the alternative, any changes that were made to Cook Tulip filter implanted in Plaintiff were reasonably foreseeable to the Cook Defendants.

75. The Cook Tulip filter implanted into Plaintiff was defective in design in the following ways:

a. It failed to perform as safely as persons who ordinarily use the product would have expected at the time of use; and,

b. Its risks of harm exceeded its claimed benefits.

76. The Cook Defendants knew that safer alternative designs were available, which would have prevented or significantly reduced the risk of the injury presented by Cook Tulip filter. Further, it was economically and technologically feasible at the time the filter left the control of the Cook Defendants to prevent or reduce the risk of such a dangerous event by application of existing, or reasonably achievable, scientific knowledge.

77. Plaintiff and Plaintiff's health care providers used the Cook Tulip filter in a manner that was reasonably foreseeable to the Cook Defendants.

78. Neither Plaintiff, nor Plaintiff's health care providers, could have, by the exercise of reasonable care, discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

79. The defective design of the Tulip filter was a producing cause of Plaintiff's injuries.

80. As a result of the Cook Tulip Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT IV
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

81. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

82. The Cook Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the Cook Tulip filter that was implanted into Plaintiff.

83. The Cook Tulip filter implanted into Plaintiff contained a condition or conditions, which the Cook Defendants did not intend, at the time it left the Cook Defendants' control and possession.

84. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Cook Defendants.

85. As a result of this condition or these conditions, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

86. As a direct and proximate result of the Cook Tulip filter's manufacturing defects, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

87. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

88. At all times relevant to this action, the Cook Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Cook Tulip filter, including the one implanted in Plaintiff, for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

89. At the time and place of sale, distribution, and supply of the Cook Tulip filter to Plaintiff by way of Plaintiff's health care providers and medical facilities, the Cook Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Cook Tulip filter was safe and effective for its intended and reasonably foreseeable use.

90. The Cook Defendants knew of the intended and reasonably foreseeable use of the Cook Tulip filter at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

91. The Cook Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Cook Tulip filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

92. The representations and implied warranties made by the Cook Defendants were false, misleading, and inaccurate because the Cook Tulip filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Cook Tulip filter from the Cook Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to an unreasonably high rate of failure, including fracture, migration, excessive tilting, causing thrombosis and/or perforation of bodily organs;

b. It was designed in such a manner so as to result in an unreasonably high rate of injury to the organs and anatomy; and,

c. It was manufactured in such a manner so that the Gunther Tulip filter system was inadequately, improperly and inappropriately prepared and/or finished, so as to be prone to an unreasonably high rate of failure and/or causing the device to fail.

93. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of the Cook Defendants as the designers, researchers, and manufacturers of the product, as to whether the Cook Tulip filter was of merchantable quality, safe and fit for its intended use and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Cook Tulip filter was manufactured and sold.

94. The Cook Defendants placed the Cook Tulip filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Cook Tulip filter was manufactured and sold.

95. The Cook Defendants breached their implied warranty because their Cook Tulip filter was not fit for its intended use and purpose.

96. As a direct and proximate result of the Cook Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT VI
NEGLIGENT MISREPRESENTATION

97. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

98. At all times relevant to this cause, and as detailed above, the Cook Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Cook Tulip filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. safety of the Cook Tulip filter;

b. efficacy of the Cook Tulip filter;

c. rate of failure of the Cook Tulip filter; and,

d. approved uses of the Cook Tulip filter.

99. The information distributed by the Cook Defendants to the public, the medical community, and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, and commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Cook Tulip filter. These materials included instructions for use and warning document that was included in the package of the Cook Tulip filter that was implanted into Plaintiff.

100. The Cook Defendants' intent and purpose in making these representations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers and Plaintiff's agents; to gain the confidence of the public and the medical community, including Plaintiff's health care providers and Plaintiff's agents; to falsely assure them of the quality of the Cook Tulip filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers, to request, recommend, prescribe, implant, purchase, and continue to use the Cook Tulip filter.

101. The foregoing representations and omissions by the Cook Defendants were in fact false. The Cook Tulip filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Cook Tulip filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without

limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

102. In reliance upon the false and negligent misrepresentations and omissions made by the Cook Defendants, Plaintiff, Plaintiff's agents, and Plaintiff's health care providers were induced to, and did use the Cook Tulip filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

103. The Cook Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, Plaintiff's agents, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by the Cook Defendants, and would not have prescribed and implanted same if the true facts regarding the device had not been concealed and misrepresented by the Cook Defendants.

104. The Cook Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Cook Tulip filter.

105. At the time the Cook Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Cook Tulip filter, Plaintiff, Plaintiff's health care providers, and the Plaintiff's agents were unaware of said the Cook Defendants' negligent misrepresentations and omissions.

106. Plaintiff's health care providers, the Plaintiff's agents, and the general medical community reasonably relied upon the foregoing misrepresentations and omissions made by the Cook Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Cook Tulip filter.

107. Plaintiff's health care providers' and Plaintiff's agents' reliance on the foregoing misrepresentations and omissions by the Cook Defendants was the direct and proximate cause of Plaintiff's injuries as described herein. As a result of the Cook Defendants' misrepresentations and omissions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PUNITIVE DAMAGES CLAIM

108. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

109. Plaintiff is entitled to an award of punitive and exemplary damages based upon the Cook Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total disregard for the public safety and welfare.

110. The Cook Defendants had knowledge of, and were in possession of evidence demonstrating that, the Cook Tulip filter was defective, unreasonably dangerous, and had a substantially higher failure rate than did other similar devices on the market. Despite their knowledge, the Cook Defendants failed to, among other purposeful acts, inform or warn Plaintiff, Plaintiff's agents, or his health care providers of the dangers, establish and maintain an adequate quality and post-market surveillance system, and recall the Cook Tulip filter from the market.

111. As a direct, proximate, and legal result of the Cook Defendants' acts and omissions as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Claude Howard, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all Cook Defendants on all causes of action of this Complaint, including but not limited to:

1. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;

2. Physical impairment and incapacity in the past and which, in reasonable probability, he will continue to suffer in the future;

3. Mental anguish in the past and which, in reasonable probability, he will sustain in the future;

4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;

5. Disfigurement in the past and which, in reasonable probability, he will continue to suffer in the future; and,

6. Punitive damages.

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of Michigan as authorized by law on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: July 28, 2021

Respectfully submitted,

/s/ Timothy P. Smith
Timothy P. Smith
Attorney for Plaintiff